COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 25-V-2005
C(2005) 1613

NOT FOR PUBLICATION

COMMISSION DECISION

of 25-V-2005

on the renewal of the marketing authorisation for the medicinal product for human use "PegIntron - Peginterferon alfa-2b", granted by Decision C(2000)1407

ONLY THE FRENCH, DUTCH TEXT IS AUTHENTIC

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(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products[1], and in particular Article 10(2) thereof,

Having regard to the application submitted by Schering Plough Europe, on 7 January 2005, under Article 13(1) of Regulation (EEC) No 2309/93 with a view to the renewal of the marketing authorisation for the medicinal product "PegIntron - Peginterferon alfa-2b"

Having regard to the opinion of the European Medicines Agency, formulated by the Committee for Medicinal Products for Human Use on 16 March 2005,

Whereas:

(1) Following consideration by the Agency of a dossier containing up-to-date information on pharmacovigilance, it appears that the medicinal product "PegIntron - Peginterferon alfa-2b" entered in the Community register of medicinal products under Nos EU/1/00/131/001-050 and authorised by Commission Decision C(2000)1407 of 25 May 2000, complies with the requirements set out in Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[2].

(2) The marketing authorisation which expires on 5 June 2005 should therefore be renewed.

(3) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on Medicinal Products for Human Use,

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[1] OJ L 214, 24.8.1993, p. 1 Regulation as last amended by [Regulation (EC) No 1647/2003 (OJ L 245, 29.9.2003, p. 19)].

[2] OJ L 311, 28.11.2001, p. 67. Directive as last amended by [Directive 2004/27/EC (OJ L 136, 30.4.2004, p.34)].

HAS ADOPTED THIS DECISION:

Article 1

The marketing authorisation granted by Decision C(2000)1407 of 25 May 2000 which expires on 5 June 2005 is renewed.

Article 2

Decision C(2000)1407 is amended as follows:

1) Annex I is replaced by the text set out in Annex I to this Decision;

2) Annex II is replaced by the text set out in Annex II to this Decision;

3) Annex III is replaced by the text set out in Annex III to this Decision.

Article 3

The period of validity of the renewed authorization shall be five years from 5 June 2005.

Article 4

This Decision is addressed to Schering Plough Europe, Rue de Stalle, 73, 1180 Bruxelles, Belgique – Stallestraat, 73 – 1180 Brussel, België.

Done at Brussels, 25-V-2005

For the Commission
Günter VERHEUGEN
Member of the Commission